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Opportunities and challenges arising in the women's health initiative clinical trial and cohort study

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The Women's Health Initiative (WHI) enrolled 161,808 postmenopausal women in the 50-79 age range into either a multi-faceted clinical trial (68,132) or a prospective cohort study (93,676) during 1993-8. The postmenopausal hormone therapy components of the clinical trial markedly changed clinical practice and led to an important reduction in national breast cancer incidence. The availability of both randomized controlled trial data and cohort study data for study subjects drawn from the same base population provides the context for an empirical evaluation of statistical modeling issues and biases in failure time data analyses. Biomarker substudies in WHI cohorts also provide the opportunity to apply novel measurement error correction procedures in studies of nutritional and physical activity exposures in relation to chronic disease risk. Also, high-dimensional blood-based biomarker assessments can usefully augment candidate biomarker studies, both for the identification of hazard ratio variations among study subjects, and for insight into biological mediators of intervention effects. The former can be efficiently conducted using case-only designs, while the latter entails relatively unexplored issues in the presence of measurement error. These opportunities and challenges will be illustrated using survival and event history analysis methods that mostly emanate from the Cox regression model.

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